REMARKS

This Amendment is submitted in response to the Non-final Office Action mailed on November 9, 2011 (the "Office Action"). The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3712161-44 on the account statement.

Claims 1, 3, 4, 5, 9-11, 13-16, 18, 19 and 21 are rejected in this application. Claims 2, 5, 7-8, 12, 17, 20 and 23-25 were previously canceled without disclaimer. In the Office Action, Claim 15 is rejected under 35 U.S.C. §112, 1st ¶. Claims 9 and 19 are rejected under 35 U.S.C. §112, 2d ¶ Claims 1, 3, 4, 5, 9-11, 13-16, 18, 19 and 21 a rejected under 35 U.S.C. §102(b). Claims 1, 3, 4, 5, 9-11, 13-16, 18, 19 and 21 are rejected under 35 U.S.C. §103(a). In response Claims 1, 3, 4, 6, 9, 10, 14-16 and 21 have been amended. The amendments do not add new matter. In view of the amendments and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

A. Claim Rejections Under 35 U.S.C. § 112, 1st ¶.

In the Office Action, Claim 15 is rejected under 35 U.S.C. §112, 1st ¶. Specifically, the Office Action states that "the specification, while being enabling for treating some health problems by using an anandamaide or one of its precursors, does not reasonably provide enablement for the prevention of [the] health problems" listed in Claim 15. (Office Action at p. 3, ¶ 3.) More specifically, the Office Action states that "there is no evidence in the prior art that the instant composition would entirely prevent all or any of the listed ailments." (*Id.*, emphasis in original.) However, the Office Action admits that the state of the prior art is high, and "a number of publications describe methods of treating different ailments using compounds comprising anandamides . . . ." (*Id.*)

In response to the Office Action, and without admitting the propriety of the instant rejection, Applicants have amended Claim 15 such that it recites, in relevant part, "method of manufacture a composition for the treatment ~~or prevention~~ of an anandamide-mediated ailment selected from the group consisting of hypertension, glaucoma, insomnia, pain, inflammation, migraine headaches, loss of appetite, nausia, cramps, diarrhoea, gut upsets, intestinal motility disturbances, asthma, nervousness, catalepsy, low mood, depression, spasms, tics, excessive stress, spasticity, multiple sclerosis and vocalization, poor language acquisition, skin

inflammation and excess nociception, ..." Accordingly, Applicants respectfully request that the enablement rejection with respect to pending Claim 15 be reconsidered and withdrawn.

B. Claim Rejections Under 35 U.S.C. § 112, 2d ¶.

In the Office Action, Claims 9 and 19 are rejected under 35 U.S.C. §112, 2d ¶, as being indefinite. Specifically, the Office Action states that Claim 9 depends upon a cancelled claim. In response, Applicants have amended pending Claim 9 to depend from pending Claim 1.

The Office Action states that "[w]ith regards to claim 19 it is unclear if the naturally occurring precursor is 'synthesized' with another material or if applicants intend to mean that the precursor is synthesized from some starting materials not described in the claim." Consistent with Applicants' statements in the Response to March 25, 2008, Office Action submitted on July 25, 2008, Applicants respectfully submit that the term "synthesize" is not indefinite to those skilled in the art. First, the term "synthesize" has a commonly accepted definition: "to combine or put together by synthesis." (Webster's Third New Int'l Dictionary at p. 2321 (1993).) In turn, "synthesis" is commonly understood by those skilled in the art to mean "the production of a chemical compound by the union of elements or simpler compounds or by the degradation of a complex compound esp. by laboratory or industrial methods." (*Id.*) Furthermore, as stated in the Specification, "the invention provides a method of production of a nutritional or therapeutic composition for oral administration which comprises the steps of identifying, purifying ***or synthesising*** a naturally occurring precursor that is metabolised to a compound having anandamide activity." (Specification at p. 4, lines 32-35, emphasis added.) Thus, the term "synthesizing" in Claim 19 is not indefinite as suggested by the Office Action because its meaning would be understood to those of ordinary skill in the art. Accordingly, Claims 9 and 19 are not indefinite under 35 U.S.C. 112, 2d ¶. Applicants respectfully request that the indefiniteness rejections be reconsidered and withdrawn.

C. Claim Rejections Under 35 U.S.C. § 102(b).

In the Office Action, Claims 1, 3-4, 6, 9-11, 13-16, 18-19 and 21 are rejected under 35 U.S.C.§ 102(b) as being anticipated by U.S. Patent No. 5,411,751 to Crissinger et al. ("*Crissinger*") as evidenced by Bennett et al., "Suppression of Renal Inflammation with Vitamins A and E in Ascending Pyelonephritis in Rat," J. Urology, vol. 61(5), pp. 1681-84 (May

1999) ("*Bennett*"). In response to the Office Action, Applicants have amended the claims to distinguish over the cited references as set forth below.

Independent Claim 1 has been amended to recite:

> An orally administrable composition comprising a steroidal or non-steroidal anti-inflammatory drug ("NSAID"), and a structured triacylglycerol comprising: a naturally occurring precursor portion at the *sn*-2 position of the structured triacylglycerol, wherein the naturally occurring precursor portion is metabolised to a compound having anandamide activity for use as a medicament, and an inhibitor of an anandamide inactivating enzyme (amidase) at the *sn*-1 and/or *sn*-3 positions of the structured triacylglycerol,
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> wherein the naturally occurring precursor comprises the acyl portion of a long chain polyunsaturated fatty acid ("LCPUFA") which is a polyunsaturated fatty acid of 16-28 carbon atoms having from 2 to 6 double bonds, and having a moiety selected from the group consisting of methyl-, branched-, cyclic-, conjugated-, non-methylene interrupted-, epoxy-, furanoid-, hydroxyl-, allylic-, trans-, and seleno, and
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> wherein the inhibitor is selected from the group consisting of oleoyl, palmitoyl, and linoleyl.

Pending independent Claims 14-16 have each been similarly amended with respect to the precursor and inhibitor components of the composition.

In contrast, the food products disclosed in *Crissinger* do not include a structured triacylglycerol comprising a naturally occurring precursor portion that has anandamide activity after metabolization and an inhibitor portion having anandamide activity.

Bennett does not cure the deficiencies of *Crissinger*. The Office Action states that *Bennett* discloses anti-inflammatory properties of Vitamins A and E. (Office Action at p. 7.) However, *Bennett* does not disclose a composition comprising a structured triacylglycerol comprising a naturally occurring precursor portion that has anandamide activity after metabolization and an inhibitor portion having anandamide activity. Accordingly, amended pending independent Claims 1 and 14-16 are not anticipated by *Crissinger* as further evidenced by *Bennett* as stated in the Office Action.

Applicants respectfully request that the anticipation rejection with respect to the pending claims be reconsidered and withdrawn.

D. Claim Rejections Under 35 U.S.C. § 103(a).

In the Office Action, Claims 1, 3-11 and 13 are rejected under 35 U.S.C. §103(a) as being unpatentable over the publication to Di Marzo ("*Marzo*") in view of U.S. Patent No. 6,552,031 to Burch et al. ("*Burch*"). Claims 14-16 and 18-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Di Marzo* in view of *Burch* and further in view of WO 94/28913 to Kyle et al. ("*Kyle*"). In response to the Office Action, Applicants have amended the claims to distinguish over the cited references as set forth below.

Independent Claim 1 has been amended to recite:

> An orally administrable composition comprising a steroidal or non-steroidal anti-inflammatory drug ("NSAID"), and a structured triacylglycerol comprising: a naturally occurring precursor portion at the *sn*-2 position of the structured triacylglycerol, wherein the naturally occurring precursor portion is metabolised to a compound having anandamide activity for use as a medicament, and an inhibitor of an anandamide inactivating enzyme (amidase) at the *sn*-1 and/or *sn*-3 positions of the structured triacylglycerol,
>
> wherein the naturally occurring precursor comprises the acyl portion of a long chain polyunsaturated fatty acid ("LCPUFA") which is a polyunsaturated fatty acid of 16-28 carbon atoms having from 2 to 6 double bonds, and having a moiety selected from the group consisting of methyl-, branched-, cyclic-, conjugated-, non-methylene interrupted-, epoxy-, furanoid-, hydroxyl-, allylic-, trans-, and seleno, and
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> wherein the inhibitor is selected from the group consisting of oleoyl, palmitoyl, and linoleyl.

Pending independent Claims 14-16 have each been similarly amended with respect to the precursor and inhibitor components of the composition.

None of the cited references discloses or suggests a structured triacylglycerol comprising a naturally occurring precursor that has anandamide activity after metabolization and an inhibitor portion having anandamide activity. In addition, the combination of the naturally occurring precursor and the amidase inhibitor in the form of a triacyclgylcerol provides the following advantages that are not disclosed in the cited references: (i) merely one compound (instead of two) has to be added to the composition facilitating its preparation in terms of solubility/mixability, (ii) the amidase inhibitor is presented in close spatial relationship with the

actual substrate—the naturally occurring precursor—to the respective converting enzymes with the consequence that the amidase will be inhibited to a higher extent, and (iii) all constituents, *i.e.,* the glycerol, the naturally occurring precursor and the amidase inhibitor, are generally considered safe fulfilling nutritional standards that assist in manufacturing and approval procedures.

Thus, the cited references alone or in combination fail to disclose or suggest a single orally administrable composition containing a steroidal or non-steroidal anti-inflammatory drug ("NSAID"), and a structured triacylglycerol comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity at the *sn*-2 position of the triacylglycerol and an inhibitor of an anandamide inactivating enzyme (amidase) at the *sn*-1 and/or *sn*-3 position of the structured triacylglycerol as required by amended independent Claims 1 and 14-16. Moreover, the cited references fail to teach or even suggest the synergistic advantages and benefits of the orally administrable composition comprising an NSAID and a structured triacylglycerol as required by the pending claims.

For at least the reasons discussed above, the cited references fail to disclose or suggest each and every element of amended independent Claims 1 and 14-16. As a result, Applicants respectfully submit that independent Claims 1 and 14-16, along with any of the claims that depend from Claims 1 and 14-16, are novel, nonobvious and distinguishable from the cited references.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to the pending claims be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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